**Official Title of Study:** Evaluating a Structural and Behavioral HIV Risk Reduction Program for Black Men

**NCT Number:** NCT01694121

**Date of Document:** February 10, 2015

**THE GEORGE WASHINGTON UNIVERSITY**
**CONSENT TO TAKE PART IN A RESEARCH STUDY: MEN Count Program**

**Title of Research:** Evaluating an Intervention Affecting Black Men's Structural and Behavioral HIV Risk

**Investigator's Name:** Lisa Bowleg, Ph.D.

**Sponsor:** National Institute of Mental Health (NIMH)

**Research Entity:** Department of Psychology

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# INTRODUCTION

**1.** You are invited to take part in a research study being conducted by Dr. Lisa Bowleg and the Department of Psychology at The George Washington University. The study is funded by the National Institute of Mental Health (NIMH).

**2.** Your participation in this study is voluntary. You may choose not to be a part of the study or you can stop participating in the study at any time you choose If at any point in the study, you wish to withdraw from the study, just tell the researcher or interviewer of your decision.

**3. Consent for the Research Study:** Please read this form and ask us any questions that will help you decide if you want to be in the study. A trained MEN Count research assistant will guide you through this form and answer any of your questions. If you sign it, you will be authorizing The George Washington University, and its researchers to perform research studies on you. You can also take a copy of this consent form to discuss it with your family member, attorney or any one else you would like before you sign it. Do not sign this form unless you are comfortable in participating in this study.

# PURPOSE

**4**. We are asking you to participate in this research study so you could help us know if a case management program helps improve risk for HIV among African American and Black men. This program is health focused plus looks at issues of housing and employment. The program integrates HIV risk reduction and gender-equity counseling with housing and employment case management. The program includes three one-on-one sessions delivered by a case manager over a 60-90 day period. Sessions will be audio recorded, but you may option out of these recordings. You will also be asked to complete a survey and HIV and STI screening during your

initial visit, and at 6 -month and 12 month follow-up visits. You may also be asked to participate in a qualitative interview after 6 months of enrolling, regardless if you remain in the program.

**5.** You have been asked to participate in this study because you are a Black/African American man between 18 – 44 years old, have had unprotected vaginal sex with a woman in the past year and more than 2 female sex partners in the past 12 months, and have been homeless in the past 6 months or are currently unemployed. You will not be able to participate in the study if you: (1) currently participate in a similar program or have participated in a similar program in past 2 years; (2) plan to leave the Washington, DC, Maryland, Virginia area in next 6 months; (3) are cognitively impaired.; or (4) have a health status that prohibits you from participating. Your participation in the study will end if you do not meet the study's criteria for participation.

**6.** We expect that 504 men will participate in the study

**7.** The purpose of this study is to evaluate the MEN Count intervention. Your participation in the study will help us learn if the MEN Count intervention is effective.

## PROCEDURE

**8.** **What Will Happen During the Study:** If you decide to participate in the study, you understand that the following will happen:

1. It is not clear whether the intervention will be effective. Because of this, all participants in the study will be randomly assigned to the intervention group or the comparison condition, which will also include a men's health focused case management program. You have about a 50/50 chance of being assigned to either group.

2. You will complete an electronic survey. During the study, a trained research assistant will use an electronic tablet to record your responses to the study's survey. If you prefer, you will complete the survey on your own and the interviewer will remain nearby, but will not look at your answers. You will be able to call the interviewer over to ask any questions that you might have. The nature of the questions that will be asked during the survey include demographic information, risk behaviors, HIV risk profile, and knowledge, attitudes, and risk perceptions about HIV.

3. After the tablet survey, a staff member will take you to a private room for counseling and testing for HIV and STI. During this screening you will be asked to provide saliva (spit) and urine (pee) for HIV/STI screening (gonorrhea and Chlamydia). Following your case management session, research staff will contact you and provide counsel. If you are identified as HIV or STI positive, we will provide you with clinical care information and referrals. GWU research staff will contact you to follow-up, should you choose to be linked to care. The HIV rapid test is a preliminary result. Positive preliminary results from the HIV rapid test will require follow-up testing to confirm HIV status.

4. Within 2 months of your initial visit you will be contacted to begin the MEN Count program. This includes 3 one-hour-long, one-on-one sessions with a case manager,

over the course of 60-90 days. You may complete your first session the same day as your baseline survey. During these sessions a case manager will work with you to link you to appropriate services and systems and monitor your progress in the program. The program will also provide you with five optional 20-minute bi-monthly check-in phone calls or meetings with the case manager. These meetings may be digitally recorded to ensure quality and adherence to the program's curriculum. However, these recordings will not be transcribed (typed up). Study staff may take notes to improve quality and adherence to the program.

5. Over the course of the program, you may be randomly selected to participate in an evaluation survey to see if the program is meeting your needs. During these survey periods we will ask you to test for HIV/STI. These survey periods will occur at 6 and 12 months. After 6 months you may also be asked to participate in a 60-90 minute in-depth qualitative interview to discuss your experience in the program. Not all participants will be asked to participate in the qualitative interview.

## RISKS AND CONFIDENTIALITY

**9. YOUR RIGHT TO PRIVACY AND CONFIDENTIALITY:** This section gives more specific information about the privacy and confidentiality of your personal information. It explains what personal information about you will be collected during this research study and who may use and receive your information.

**10.** All materials relevant to your participation in the study will be confidential. Neither your name nor any other information that could identify you will be linked to any of the information you provide during the study or in any of the study's reports or publications. The information that you provide on the electronic survey will be saved using a code number. Then that electronic file will be transferred from the tablet that you used to a secure server. This server is password protected so that only Dr. Lisa Bowleg and other authorized members of the research team will have access to. In any publication or presentation of research results, your identity will be kept confidential.

**A.** Individually Identifiable Information that will be collected
The following personal information about you will be collected and used during the research study:

- Your name, address, telephone number, date of birth;
- Information learned during telephone calls, HIV/STI testing, surveys, questionnaires and office visits done as part of this research study;

**B.** Sensitive Information that will be collected
The research investigator and research team may request information about sexual practices, drug use, and other illegal activity as part of the study.

**C.** Who will see and use your personal information within George Washington University.

The research study investigator and other authorized individuals involved in the research study at George Washington University will see your information. These include the research investigator and the research staff, the institutional review board and their staff, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly.

**C.** Who else may see and use your personal information.

Other persons and organizations outside of George Washington University may see and use your personal information during this research study. These include:

- Governmental entities that have the right to see or review your health information, such as the Office of Human Research Protections
  - The research data management organization that is analyzing data collected during this research study. The name of the organization is The University of California San Diego.
  - An outside institutional review board such as at The University of California, San Diego.

**D.** Certificate of Confidentiality:

We will do everything we can to keep others from learning about your participating in this study. To help keep information about you confidential, the researchers have obtained a Confidentiality Certificate from the United States Department of Health and Human Services (DHHS). With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study.

If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.
This Certificate does not represent an endorsement of the research project by DHHS.

**E.** Mandated Reporting and Involvement of Authorities

The Certificate of Confidentiality will not be used to prevent disclosure to local authorities of child abuse and neglect, and to prevent serious harm to the subject or others (e.g., perpetration of homicide, child abuse, or elder abuse; suicidality; homicidal intentions). We will also immediately refer you to mental health services care at the local medical care agency if you disclose that they are suicidal or homicidal.

**11. Risks and Discomforts:** A potential risk of your participation in the study is that you may feel uncomfortable answering questions about your personal attitudes, beliefs and behaviors, especially sexual behaviors. Remember however, that all of the information that you provide is confidential. None of the study's reports or publications will use your name or any other identifying information. Only authorized members of the research team will have access to your information. Research staff members working with this study will be required to maintain confidentiality of all research participants and will be required to sign a pledge agreeing to do so upon joining the study. Although there may be an instance of a breach of confidentiality if individuals outside of the MEN Count research team and staff get access to this data.

Regarding HIV testing, researchers will answer any questions that you may have about HIV/AIDS. Should you test positive, you will be linked to HIV services by a research staff member. You will also be contacted by GWU research staff to confirm linkage to care. All participants will be counseled on the following:

1. HIV is the virus that causes AIDS and can be transmitted through unprotected sex (vaginal, anal, or oral sex) with someone who has HIV; contact with blood as in sharing needles (piercing, tattooing, drug equipment including needles), by HIV-infected pregnant women to their infants during pregnancy or delivery, or while breast feeding.
2. There are treatments for HIV/AIDS that can help an individual stay healthy.
3. Individuals with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from becoming infected or being infected themselves with different strains of HIV.
4. The law protects the confidentiality of HIV test results and other related information.
5. The law prohibits discrimination based on an individual's HIV status and services are available to help with such consequences.
6. The law allows an individual's informed consent for HIV related testing to be valid for such testing until such consent is revoked by the subject of the HIV test or expires by its terms.

If you find that any potential risks or discomfort occur, you may stop your participation in the study at any time. You will also be able to call the study's investigator, Dr. Lisa Bowleg, or the study's Project Director, Jenné Massie to discuss any discomfort that you experienced during the study.

**12. Unforeseen Risks:** If any other risks that we have not thought about ahead of time (i.e., unforeseen risks) occur, they will be reported to the **GWU office of Human Research at 202-994-2715.**

## BENEFITS OF PARTICIPATION / ALTERNATIVE PROCEDURES

13. **Benefits of your Participation in the Study:** Through your participation, you will receive referrals to local health and social services. You participation in this study will also assist the researcher by providing information on the Men Count intervention and in community HIV prevention service delivery, which is sorely needed to help address HIV in Black communities. At the end of your participation, you may also have the opportunity to provide contact information to an anonymous phone or email list to be notified of any study results, upcoming events or projects related to this study.

**14. Alternative Procedures:** If you decide that you do not want to participate in the MEN Count intervention and evaluation, you may be eligible to participate in other programs. You may also access free HIV and STI testing in Washington, DC. Please let the researcher know if you would be interested in participating in one of these other procedures.

**15. REASONS FOR REMOVAL FROM STUDY:** You may be required to stop the study before the end for any of the following reasons:

a) Change in medical condition;
b) You become incarcerated during the pilot study
c) If all or part of the study is discontinued for any reason by the sponsor, investigator, university authorities, or government agencies; or
d) Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by the subject or other subjects in this study.

**16. Voluntary Participation:** Participation in this study is voluntary, and you can refuse to be in the study or stop at any time. There will be no negative consequences if you decide not to participate or to stop. If you withdraw from the study you will be compensated for your time dependent on the surveys already completed prior to leaving the study.

## PAYMENT AND COMPENSATION

**17. Reimbursement:** At the end of each of your visits to complete the tablet-based survey & HIV/STI testing you will receive a $30 cash reimbursement at baseline, $40 cash at 6 month follow-up, and $50 cash at 12 month follow-up.

**19. Paid Referrals:** You will be paid $10 for successfully referring other men to the study. Successful referrals are men that are eligible, complete their first session, and identify you as their reference during enrollment. You will be provided with 3 to 5 referral coupons during enrollment. You will be paid up to $30-50 for successful referrals. The number of referral coupons provided to each participant will be based on the current needs of the study.

**20. Tablet Raffle**: You will be given a single ticket entry for the raffle of an electronic tablet.

**21. Responsibility for Costs:** If HIV or STI screenings are positive, the MEN Count Program has partnered with the HAHSTA Southeast STD Clinic to help you find a place to get testing and treatment.

## Other Considerations

If you wish further information regarding your rights and welfare as a research participant please contact the GWU office of Human research at 202-994-2715. If you have problems with a research-related injury or for medical problems please contact the Principal Investigator, Lisa Bowleg at 202-994-1367.

# DOCUMENTATION OF CONSENT

After reading this form, you can sign below to show that you agree that your personal information may be used and disclosed during this research study. We will only collect information that is needed for the research study. Your personal information will only be used and given out as explained in this consent form or as permitted by law. By signing below you are indicating that a MEN Count research assistant has explained this consent form to you and answered all of your questions and that you understand the content of this form.

**Participant Signature:** _____ **Date:** _____

List of Individuals Authorized to Obtain Consent:

| Name | Title | Day Phone # | 24 Hr Phone # |
|---|---|---|---|
| Dr. Lisa Bowleg | Principal Investigator | 202-994-1367 | 202-994-1367 |
| Jenné Massie | Project Director | 202-994-0603 | 202-994-0603 |
| Sidney Holt | Research Assistant | 202-994-1384 | 202-994-1384 |
| Amanda Allison-Pacheco | Research Assistant | 202-994-1384 | 202-994-1384 |
| Bria Roach | Research Assistant | 202-994-1384 | 202-994-1384 |
| Sadaf Ahari | Research Assistant | 202-994-1384 | 202-994-1384 |
| Victoria Montero | Research Assistant | 202-994-1384 | 202-994-1384 |

**THE GEORGE WASHINGTON UNIVERSITY**
**CONSENT TO TAKE PART IN A RESEARCH STUDY:**
**MEN Count Qualitative Interviews (CASE MANAGER CONSENT)**

**Title of Research:** Evaluating an Intervention Affecting Black Men's Structural and Behavioral HIV Risk

**Investigator's Name:** Lisa Bowleg, Ph.D.

**Sponsor:** National Institute of Mental Health (NIMH)

**Research Entity:** Department of Psychology

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# INTRODUCTION

**1.** You are invited to take part in in-depth interviews as part of a research study being conducted by Dr. Lisa Bowleg, Department of Psychology at The George Washington University. The study is funded by the National Institute of Mental Health (NIMH).

**2.** You are being asked to take part in the in-depth interview because you provide case management in the MEN Count study. We are asking all active MEN Count case managers to participate in the interviews on a biannual basis.

**3.** Your participation in this in-depth interview is voluntary. You may choose not to participate in the interview, or you can stop participating in the interview at any time you choose, without consequence. If at any point in the interview you wish to stop the interview, just tell the researcher or interviewer of your decision. Your employment status will not be affected if you declined to participate in this study or stopped participation in this study for whatever reason, at any time.

**4. Consent for the In-Depth Interview:** Please read this form and ask us any questions that will help you decide if you want to be interviewed. This is a long and important document. If you sign it, you will be authorizing The George Washington University, and its researchers to perform research studies on you. You should take your time and carefully read it. You can also take a copy of this consent form to discuss it with your family member, attorney or anyone else you would like before you sign it. Do not verbally agree to this form unless you are comfortable in participating in this study.

# PURPOSE

**5**. We are asking you to participate in this research in-depth interview so that you can help us know if the MEN Count case management program helps reduce Black/African American

men's HIV risk. The MEN Count program entailed the provision of three one-on-one sessions that you, as a case manager, delivered over a 60-90 day period.

**6.** You were asked to participate in the original study because you are a MEN Count case manager.

**7.** We expect that 2-5 men will participate in the in-depth interview of case managers component of the study.

**8.** The purpose of this portion of the MEN Count is to better understand how effective Men Count has been in meetings its goal. Your participation in this phase of the study will help us learn if the MEN Count intervention is effective.

**9**. Your participation in this part of the study is voluntary. You may choose not to be a part of this part of the study or you can stop participating at any time you choose. If at any point in the interview, you wish to withdraw from it, just tell the researcher or interviewer of your decision.

## PROCEDURE

**10. What Will Happen During the In-Depth Interview:** If you decide to participate, you understand that the following will happen:

1. You will complete a 60 minute qualitative interview, to discuss your experience with the MEN Count program. A trained research assistant will digitally audio-record your responses. The nature of the questions that you will be asked during the survey include questions related to your perception about the MEN Count program, including what limitations you think exist in implementing the program (implementation data), program successes and barriers, how accessible the program was for participants, participant's engagement with the program, what you think the impact of the program was, how to improve and sustain the program, and issues relevant to program staffing and training.

## RISKS AND CONFIDENTIALITY

**11. YOUR RIGHT TO PRIVACY AND CONFIDENTIALITY:** This section gives more specific information about the privacy and confidentiality of your personal information. It explains what personal information about you will be collected during this interview and who may use and receive your information.

**12.** All materials relevant to your participation in the study will be confidential. Neither your name nor any other information that could identify you will be linked to any of the information you provide during the study or in any of the study's reports or publications. The evaluation team will keep the information from this interview confidential. They will use quotes to illustrate key themes in reports, but will not identify you by name or any other identifiers. If we use any of the information you provide, we will make up a name and change any information that someone

could use to identify you. In any publication or presentation of research results, your identity will be kept confidential.

**A.** Individually Identifiable Information that will be collected
The following personal information about you will be collected and used:

- Information learned during this interview related to the case management sessions completed (or not completed) as part of this research study;

**B.** Sensitive Information that will be collected
As part of the interview, the interviewer may ask about your experiences and comfort level about some of the intervention topics during the study.

**C.** Who will see and use your personal information within George Washington University.
The research study investigator and other authorized individuals involved in the research study at George Washington University will see your information. These include the research investigator and the research staff, the institutional review board and their staff, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly.

**C.** Who else may see and use your personal information.
Other persons and organizations outside of George Washington University may see and use your personal information during this in-depth interview, which is part of the larger research study. These include:

- The research data management organization at the University of California, San Diego that is analyzing data collected during this research study.
- An outside institutional review board, such as at the University of California, San Diego.

**D.** Mandated Reporting and Involvement of Authorities
The Certificate of Confidentiality will not be used to prevent disclosure of child abuse and neglect to local authorities, and to prevent serious harm to the subject or others (e.g., perpetration of homicide, child abuse, or elder abuse; suicidality; homicidal intentions). We will also immediately refer you to mental health services care at the local medical care agency if you disclose that you are suicidal or homicidal.

**13. Risks and Discomforts:** A potential risk of your participation in the interview is that you may feel uncomfortable answering questions about your employment experiences with MEN Count. Remember however, that all of the information that you provide is confidential, and we will ask no information regarding your supervision experiences. None of the study's reports or publications will use your name or any other identifying information. Only authorized members of the research team will have access to your information. Research staff members working with this study will be required to maintain confidentiality of all research participants and have, or will be required to sign a pledge agreeing to do so when they joined the study. There may be an a

breach of confidentiality if individuals outside of the MEN Count research team and staff get access to this data.

If you find that any potential risks or discomfort occur, you may stop your participation in the interview at any time. You will also be able to call the study's investigator, Dr. Lisa Bowleg, or the study's Project Director, Jenné Massie to discuss any discomfort that you experienced during the interview.

**14. Unforeseen Risks:** If any other risks that we have not thought about ahead of time (i.e., unforeseen risks) occur, they will be reported to the **GWU office of Human Research at 202-994-2715.**

## BENEFITS OF PARTICIPATION / ALTERNATIVE PROCEDURES

15. **Benefits of your Participation in the Interview:** Your participation in this study will also assist the researcher by providing information on the Men Count intervention and on community HIV prevention service delivery, which is sorely needed to help address HIV in Black communities. As always, at the end of the interview, you will have the opportunity to provide contact information to an anonymous phone or email list to be notified of any study results, upcoming events or projects related to this study.

**16. Alternative Procedures:** If you decide that you do not want to participate in this in-depth interview for the MEN Count intervention and evaluation, there are no other alternative procedures.

**17. REASONS FOR REMOVAL FROM THE INTERVIEW:** You may be required to stop the study before the end for any of the following reasons:

a) If all or part of the study is discontinued for any reason by the sponsor, investigator, university authorities, or government agencies.

**18. Voluntary Participation:** Participation in this in-depth interview as a part of this study is voluntary, and you can refuse to participate in the interview or stop at any time. There will be no negative consequences if you decide not to participate or to stop.

## PAYMENT AND COMPENSATION

**19. Reimbursement:** Because case managers are employees of the study, there will be no reimbursement for participation in the study.

**20. Responsibility for Costs:** There are no financial costs associated with participating in this interview.

## Other Considerations

If you wish to get more information about your rights and welfare as a research participant please contact the GWU office of Human research at 202-994-2715. If you have problems with a

research-related injury or for medical problems please contact the Principal Investigator, Dr. Lisa Bowleg at 202-994-1367.

## DOCUMENTATION OF CONSENT

After reading this form, you can verbally agree that your personal information may be used and disclosed during this research study. We will only collect information that is needed for the research study. Your personal information will only be used and given out as explained in this consent form or as permitted by law.

List of Individuals Authorized to Obtain Consent:

| Name | Title | Day Phone # | 24 Hr Phone # |
|---|---|---|---|
| Dr. Lisa Bowleg | Principal Investigator | 202-994-1367 | 202-994-1367 |
| Jenné Massie | Project Director | 202-994-1384 | 202-994-1384 |
| Sidney Holt | Research Assistant | 202-994-1384 | 202-994-1384 |
| Dave Jean | Research Assistant | 202-994-1384 | 202-994-1384 |
| Amanda Allison-Pacheco | Research Assistant | 202-994-1384 | 202-994-1384 |
| Bria Roach | Research Assistant | 202-994-1384 | 202-994-1384 |
| Sadaf Ahari | Research Assistant | 202-994-1384 | 202-994-1384 |
| Victoria Montero | Research Assistant | 202-994-1384 | 202-994-1384 |

**THE GEORGE WASHINGTON UNIVERSITY**
**CONSENT TO TAKE PART IN A RESEARCH STUDY:**
**MEN Count Qualitative Interviews (STUDY PARTICIPANT CONSENT)**

**Title of Research:** Evaluating an Intervention Affecting Black Men's Structural and Behavioral HIV Risk

**Investigator's Name:** Lisa Bowleg, Ph.D.

**Sponsor:** National Institute of Mental Health (NIMH)

**Research Entity:** Department of Psychology

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## INTRODUCTION

**1.** You are invited to take part in an in-depth interview as part of a research study being conducted by Dr. Lisa Bowleg, Department of Psychology at The George Washington University. The study is funded by the National Institute of Mental Health (NIMH).

**2.** You are being asked to take part in this in-depth interview because you currently are, or were, enrolled and participated in the Men Count study.

**3.** Your participation in this in-depth interview is voluntary. You may choose not to participate in the interview, or you can stop participating in the interview at any time you choose. If at any point in the interview you wish to stop the interview, just tell the researcher or interviewer of your decision.

**4. Consent for the In-Depth Interview:** Please read this form and ask us any questions that will help you decide if you want to be interviewed. This is a long and important document. If you sign it, you will be authorizing The George Washington University, and its researchers to perform research studies on you. You should take your time and carefully read it. You can also take a copy of this consent form to discuss it with your family member, attorney or anyone else you would like before you sign it. Do not verbally agree to this form unless you are comfortable in participating in this study.

## PURPOSE

**5**. We are asking you to participate in this research in-depth interview so that you can help us know if a case management program helps reduce Black/African American men's HIV risk. The program you enrolled and potentially participated in, included three one-on-one sessions delivered by a case manager over a 60-90 day period. During the study, you were asked to complete a survey and HIV and STI screening during your initial visit, as well as at 6 -months and 12 months after you completed your sessions. You are now being asked to participate in a

qualitative interview 6 months after enrolling, regardless of whether you remained in the program.

**6.** You were asked to participate in the original study because at the time of enrollment, you were a Black/African American man of at least the age of 18, have had unprotected vaginal sex with a woman in the past year and more than 2 female sex partners in the past 12 months, and had been homeless and/or unemployed in the past 6 months.

**7.** We expect that 50 men will participate in the in-depth interview component of the study.

**8.** The purpose of this portion of the MEN Count is to better understand how effective Men Count has been in meetings its goal. Your participation in this phase of the study will help us learn if the MEN Count intervention is effective.

**9**. Your participation in this part of the study is voluntary. You may choose not to be a part of this part of the study or you can stop participating at any time you choose. If at any point in the interview, you wish to withdraw from it, just tell the researcher or interviewer of your decision.

## PROCEDURE

**10. What Will Happen During the In-Depth Interview:** If you decide to participate, you understand that the following will happen:

1. You will complete a 60 minute qualitative interview to discuss your experience in the MEN Count program. A trained research assistant will digitally audio-record your responses. The nature of the questions that will be asked during the survey include questions related to demographics, how the program affected your housing situation, employment situation, masculinity ideologies, and sexual relationships with women. The audio recording of your interview will be typed into a word document by a professional transcriptionist for analysis.

## RISKS AND CONFIDENTIALITY

**11. YOUR RIGHT TO PRIVACY AND CONFIDENTIALITY:** This section gives more specific information about the privacy and confidentiality of your personal information. It explains what personal information about you will be collected during this interview and who may use and receive your information.

**12.** All materials relevant to your participation in the study will be confidential. Neither your name nor any other information that could identify you will be linked to any of the information you provide during the study or in any of the study's reports or publications. The evaluation team will keep the information from this interview confidential. They will use quotes to illustrate themes in reports, but will not identify you by name or use any other identifiers. If we use any of the information you provide, we will make up a name and change any information that someone

could use to identify you. In any publication or presentation of research results, your identity will be kept confidential.

**A.** Individually Identifiable Information that will be collected
The following personal information about you will be collected and used:

- Information learned during this interview related to the questionnaires and office visits completed (or not completed) as part of this research study;

**B.** Sensitive Information that will be collected
The interviewer may inquire about changes in your sexual practices, drug use, and other illegal activity as part of the interview.

**C.** Who will see and use your personal information within George Washington University.
The research study investigator and other authorized individuals involved in the research study at George Washington University will see your information. These include the research investigator and the research staff, the institutional review board and their staff, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly.

**C.** Who else may see and use your personal information.
Other persons and organizations outside of The George Washington University may see and use your personal information during this in-depth interview, which is part of the larger research study. These include:

- The research data management organization at The University of California, San Diego that is analyzing data collected during this research study.
- An outside institutional review board such as at The University of California, San Diego.

**D.** Mandated Reporting and Involvement of Authorities
The Certificate of Confidentiality will not be used to prevent disclosure of child abuse and neglect, and to prevent serious harm to the subject or others (e.g., perpetration of homicide, child abuse, or elder abuse; suicidality; homicidal intentions) to local authorities. We will also immediately refer you to mental health services care at the local medical care agency if you disclose that you are suicidal or homicidal.

**13. Risks and Discomforts:** A potential risk of your participation in the interview is that you may feel uncomfortable answering questions about changes to your personal attitudes, beliefs and behaviors, especially sexual behaviors. Remember however, that all of the information that you provide is confidential. None of the study's reports or publications will use your name or any other identifying information. Only authorized members of the research team will have access to your information. Research staff members working with this study will be required to maintain confidentiality of all research participants and will be required to sign a pledge agreeing to do

so upon joining the study. There may be an instance of a breach of confidentiality if individuals outside of the MEN Count research team and staff get access to this data.

If you find that any potential risks or discomfort occur, you may stop your participation in the interview at any time. You will also be able to call the study's investigator, Dr. Lisa Bowleg, or the study's Project Director, Jenné Massie to discuss any discomfort that you experienced during the interview.

**14. Unforeseen Risks:** If any other risks that we have not thought about ahead of time (i.e., unforeseen risks) occur, they will be reported to the **GWU office of Human Research at 202-994-2715.**

## BENEFITS OF PARTICIPATION / ALTERNATIVE PROCEDURES

15. **Benefits of your Participation in the Interview:** Your participation in this study will also assist the researcher by providing information on the Men Count intervention and on community HIV prevention service delivery, which is sorely needed to help address HIV in Black communities. As always, at the end of the interview, you will have the opportunity to provide contact information to an anonymous phone or email list to be notified of any study results, upcoming events or projects related to this study.

**16. Alternative Procedures:** If you decide that you do not want to participate in this in-depth interview for the MEN Count intervention and evaluation, you may be eligible to participate in other programs. You may also access free HIV and STI testing in Washington, DC. Please let the researcher know if you would be interested in participating in one of these other procedures.

**17. REASONS FOR REMOVAL FROMTHE INTERVIEW:** You may be required to stop the study before the end for any of the following reasons:

a) Change in medical condition;
b) You become incarcerated during the study;
c) If all or part of the study is discontinued for any reason by the sponsor, investigator, university authorities, or government agencies; or
**d)** Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by the subject or other subjects in this study**.**

**18. Voluntary Participation:** Participation in this in-depth interview as a part of this study is voluntary, and you can refuse to participate in the interview or stop at any time. There will be no negative consequences if you decide not to participate or to stop. Any fee you may be paid will be determined by the amount of time you spend in the study, and if you do not complete the interview, the reason for leaving the interview early.

## PAYMENT AND COMPENSATION

**19. Reimbursement:** If you participate in the in-depth qualitative interview you will receive $50 cash at the end of the interview.

**20. Responsibility for Costs:** There are no financial costs associated with participating in this interview.

## Other Considerations

If you wish for further information regarding your rights and welfare as a research participant please contact the GWU office of Human research at 202-994-2715. If you have problems with a research-related injury or for medical problems please contact the Principal Investigator, Dr. Lisa Bowleg at 202-994-1367.

## DOCUMENTATION OF CONSENT

After reading this form, you can verbally agree that your personal information may be used and disclosed during this research study. We will only collect information that is needed for the research study. Your personal information will only be used and given out as explained in this consent form or as permitted by law.

List of Individuals Authorized to Obtain Consent:

| Name | Title | Day Phone # | 24 Hr Phone # |
|---|---|---|---|
| Dr. Lisa Bowleg | Principal Investigator | 202-994-1367 | 202-994-1367 |
| Jenné Massie | Project Director | 202-994-1384 | 202-994-1384 |
| Sidney Holt | Research Assistant | 202-994-1384 | 202-994-1384 |
| Dave Jean | Research Assistant | 202-994-1384 | 202-994-1384 |
| Amanda Allison-Pacheco | Research Assistant | 202-994-1384 | 202-994-1384 |
| Bria Roach | Research Assistant | 202-994-1384 | 202-994-1384 |
| Sadaf Ahari | Research Assistant | 202-994-1384 | 202-994-1384 |
| Victoria Montero | Research Assistant | 202-994-1384 | 202-994-1384 |